



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

St. Jude Medical  
c/o Ms. Teri Gilio  
Sr. Regulatory Affairs Specialist  
6901 Preston Road  
Plano, TX 75024

APR 20 2012

Re: K113611

Trade/Device Name: Rapid Programmer  
Regulation Number: 21 CFR 882.5880  
Regulation Name: Implanted Spinal Cord Stimulator for Pain Relief  
Regulatory Class: Class II  
Product Code: GZB  
Dated: March 22, 2012  
Received: March 23, 2012

Dear Ms. Gilio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic, Neurological,  
and Ear, Nose and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

### Indications for Use Statement

510(k) Number (if known): K113611

Device Name(s): Rapid Programmer

The SJM Neurostimulation system is indicated for Spinal Cord Stimulation (SCS) in the treatment of chronic pain of trunk and limbs, either as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach.

The Rapid Programmer is intended to assist clinicians in determining the optimum performance while automatically logging procedures data. Rapid Programmer allows the clinician to optimize performance by leading the patient through a series of device parameter combinations and recording the stimulation effects. This system uses a touch screen computer to program the stimulator to the required waveforms and electrode configurations and to log the information derived.

Prescription Use X or Over-The-Counter Use     
(Per 21 CFR 801.109)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

KRISTEN BOWSHER

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,  
Nose and Throat Devices

510(k) Number K113611